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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,348	03/24/2005	Ilan Shalev	331/04204	5391

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,348	SHALEV, ILAN	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19-48 and 50-53* is/are pending in the application.

4a) Of the above claim(s) *25,36-38,40-43,48 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,19-24,26-35,39,44-47 and 51-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 November 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/09/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 7 2008 has been entered.

Election/Restrictions

2. Amended claim 50 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 50 is drawn to an apparatus having extensions which do not provide a channel of fluid communication through which a fluid sample can be conducted to outside of the body channel. Claim 50 is therefore drawn to a nonelected species as the elected species (shown in Figures 2A, 2B, 2C, and 2D) has extensions which do provide a channel of fluid communication through which a fluid sample can be conducted to outside of the body channel (line 28 of page 11 to line 20 of page 12). Applicant's arguments in lines 11-29 of page 10 have been considered but are not persuasive. The extensions (122) in Figures 2A, 2B, 2C, and 2D do provide a channel of fluid communication through which a fluid sample can be conducted to outside of the body tissue. For example, the extensions (122) in Figure 2B provide a channel between the extensions where the channel is seen at 276 and this

channel is capable of being a fluid communication channel through which a fluid sample can be conducted to outside of the body tissue.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 50 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hollow tube being comprised of a thicker section outside of the body than inside of the body must be shown or the feature(s) canceled from the claim(s). Also, the hollow tube being winged must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 51, it is unclear whether the recitation of the body in line 2 refers to the patient's body or a body of the apparatus.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-15, 19-24, 26-30, 32-35 39, 44-47, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (U.S. Patent No. 5,857,998).

Barry discloses an apparatus having a hollow tube (30) defining at least one aperture (40, 42, 47, 52 – lines 59-66 of column 7, 233 – lines 45-55 of column 10) configured for the intake of fluid and located on the hollow tube and at least one extension (35, 36) operative to be at at least two positions with respect to the at least one aperture. In the first position, the extension is near at least one aperture. In the second position, at least part of the extension extends away from at least one aperture. If the at least one aperture is blocked by an impediment, the relative movement of the at least one extension with respect to the at least one aperture is considered to be capable of dislodging the impediment from the at least one aperture. Barry discloses the apparatus substantially as claimed. Even though Barry disclose the apparatus may be used in any of the diverse passageways in a patient's body (lines 34-44 of column 6) and, thus, the dimensions (such as length and diameter) of the hollow tube will be selected according to the intended use of the apparatus, Barry is silent on the specifics of the hollow tube having a length of not more than 10 cm. The instant disclosure describes the parameter of length as being merely preferable, and does not describe it contributing any unexpected results to the tube. As such, the parameter of length is deemed a matter of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Applicant should note that in line 28 of page 13 to line 2 of page 14 of Applicant's specification, the length of the hollow tube is disclosed as being less than 10 cm or as being greater than 10 cm (i.e., as calculated when the length of the portion of the hollow tube within the body is added to the length of the portion of the hollow tube

that is outside of the body). This disclosure of the length of the hollow tube as being less than or greater than 10 cm is seen as being merely preferable and, therefore, there is a lack in criticality for the parameter of length of the hollow tube.

As to claim 2, the at least one aperture comprises a front inlet at a front end of the hollow tube. As to claim 3, the at least one aperture comprises one or more side openings in a side of the hollow tube. As to claim 4, the at least one aperture comprises at least one front opening at a front end of the hollow tube and at least one side opening in a side of the hollow tube. As to claims 5-10, in the Figures, Barry shows an impediment in the form of an aggregate of solid material, a venous valve, or an inflamed body tissue and which is located down flow from the hollow tube or at least partly within the hollow tube. The apparatus is structured such that moving the at least one extension from the first position to the second position would allow for the displacement of an impediment which is located down flow from the hollow tube or at least partly within the hollow tube. As to claims 11 and 12, Barry teaches that the apparatus may be left in a the patient's body between treatments (lines 21-26, column 9) and disclose the claimed structural elements of the device, thus, the device of Barry is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 13-15, 19, and 20, the apparatus includes an activating mechanism which causes the at least one extension to extend from the first position to the second position or to un-extend from the second position to the first position where the activating mechanism is configured for manual activation due to the manual operation of the apparatus and for automatic activation as a result of the delivery of inflation fluid. As to

claims 21-24, Barry discloses the claimed structural elements of the apparatus, thus, the apparatus of Barry is capable of being adapted such that delivery of the fluid may be performed before, after, or during the movement of the at least one extension or such that at least some of the movement of the at least one extension takes place irrespective of the delivery of the fluid through the at least one aperture. As to claims 26 and 27, the at least one aperture (40) is covered or arranged to be covered by the at least one extension in the first position. As to claims 28-30, the apparatus comprises a material that is capable of preventing or retarding aggregation of solid from a bodily fluid or clot formation or body tissue inflammatory response (lines 10-28 of column 8). As to claims 32-35, the at least one extension (35, 36) comprises at least one expandable element which expands when filled with expansion fluid, the apparatus includes an activating mechanism with a reservoir containing expansion fluid which is used to expand the extension, and the expansion fluid comprises a material that affects the formation of impediments and the at least one expandable element is at least partly impermeable to the material (lines 29-50 of column 8 and lines 9-30 of column 9). As to claim 39, the at least one extension comprises resilient extensions. As to claims 44 and 45, Barry teaches that the apparatus may be adapted for veins, arteries, and other locations in a patient's body and discloses the claimed structural elements of the device, thus, the apparatus of Barry is capable of being adapted for an arm vein and for an non-vein vessel (lines 34-44 of column 6). As to claims 46 and 47, the at least two positions are axially displaced and radially displaced. As to claim 53, the hollow tube is a port.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Zadno-Azizi (U.S. Patent No. 6,958,059). Barry discloses the apparatus substantially as claimed. However, Barry is silent on the specifics of the apparatus comprising a material that prevents or retards bacteria colonization. Zadno-Azizi discloses an apparatus for treating an impediment which comprises a material which is capable of preventing or retarding bacteria colonization (see line 44 of column 13 to line 6 of column 14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus of Barry with a material to prevent or retard bacteria colonization as both Barry and Zadno-Azizi disclose apparatus for treating impediments and Zadno-Azizi teaches that it is well known to provide the apparatus with a material such as an antibiotic to prevent or retard bacteria colonization as bacteria colonization can lead to complications for the patient undergoing the medical procedure.

9. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Miller et al (U.S. Patent No. 5,683,640). Barry discloses the apparatus substantially as claimed. However, Barry is silent on the specifics of the hollow tube comprising a thicker section outside of the body than inside of the body and the hollow tube being winged. Miller et al disclose a hollow tube (10) defining at least one aperture (13) configured for the intake of fluid and located on the hollow tube where the hollow tube has a thicker section (19) on the proximal part of the hollow tube that would be located outside of a patient's body and where the hollow tube is winged (31). It would have been obvious to one having ordinary skill in the art at the time the

invention was made to provide the hollow tube of Barry with a thicker section on the proximal part of the hollow tube as taught by Miller et al as Miller et al teach that it is well known to provide a thicker section (19) on the proximal part of the hollow tube to allow for support for the hollow tube, to provide strain relief, and to prevent bending of the proximal part of the hollow tube while it is being used (lines 46-52 of column 3). Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the hollow tube of Barry with a winged section on the proximal part of the hollow tube as taught by Miller et al as Miller et al teach that it is well known to provide a winged section (31) on the proximal part of the hollow tube to allow the hollow tube to be secured to the patient.

Response to Arguments

10. Applicant's arguments with respect to claims 1-15, 19-24, 26-30, 32-35, 39, and 44-47 have been considered but are moot in view of the new ground(s) of rejection. As to Applicant's arguments in lines 16-23 of page 11, even though Barry teaches positioning a stent in a patient's vessel, there is no teaching in Barry that the stent would have to be positioned in a vessel which is located more than 10 cm from the catheter's point of entry in a vein or that the delivery of the therapeutic agents to the stent would require a hollow tube that is more than 10 cm long. As to Applicant's arguments in line 24 of page 11 to line 25 of page 12, even though Barry teaches a catheter for treating cardiovascular diseases, Barry also discloses the use of the apparatus for treatment to other parts of the body (lines 10-28 of column 8) and further

discloses that the apparatus may be used in any of the diverse passageways in the patient's body such as body canals, blood vessels, ducts, etc. (lines 23-26 of column 3, lines 34-44 of column 6, and lines 66 of column 8 to line 31 of column 9). Therefore, the length of the hollow tube would be chosen based on the specific application of the claimed apparatus. As to the arguments that Barry explicitly describes a catheter to be used as a common angioplastic catheter, in lines 20-23 of column 10 of Barry, it is disclosed that the embodiment can **also** be used as a common angioplastic catheter and, therefore, the apparatus of Barry is described as being capable of being used for angioplasty as well as for other treatments in any of the diverse passageways as indicated above. It should be noted that the chosen length of the hollow tube would also be dependent on other factors such as the size of the patient and/or the size and location of the treatment site. Furthermore, the length of the hollow tube being no more than 10 cm lacks criticality as indicated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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